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Leveraging digital innovations to enhance diversity & inclusion in clinical research

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ABSTRACT

Diverse participation in clinical research is essential for equitable healthcare, yet racial and ethnic minorities remain underrepresented, undermining the generalizability of findings. The coronavirus disease 2019 (COVID-19) pandemic catalyzed the adoption of digital innovations—such as decentralized trials, telehealth, and artificial intelligence—to enhance recruitment and inclusion in underserved populations. However, persistent challenges, including mistrust and data variability, necessitate robust regulatory frameworks. Mandating diversity guidelines, enforcing compliance, and integrating digital strategies are critical to fostering inclusivity, ensuring clinical research equitably serve all populations.

Key words: artificial intelligence, COVID-19, digital innovation, health equity, pharmaceutical industry

INTRODUCTION

Clinical trials are the cornerstone of groundbreaking advancements in modern medicine. However, their real promise hinges on diverse participation. Historically, clinical trials have exclusively enrolled Caucasian participants, resulting in a significant gap in understanding how medical treatments impact other racial and ethnic groups. This underrepresentation not only limits the robustness and generalizability of trial findings but also perpetuates health disparities.[1–4] Addressing this imbalance is crucial for improving patient outcomes and ensuring that all demographic groups benefit from medical research. The onset of the coronavirus disease 2019 (COVID-19) pandemic has been catalytic for rethinking strategies to enhance diversity and inclusion in clinical trials.[5,6] The advent of artificial intelligence (AI) and digital technologies offers a promising solution to facilitate clinical research involvement among underserved and underrepresented communities.[7,8] This article explores the transformative potential of digital innovations in improving diversity and inclusion within clinical research, discussing regulatory guidance, key technologies, and presenting case studies of strategic initiatives aimed at fostering inclusivity and equitable representation.

IMPORTANCE OF DIVERSITY AND INCLUSION IN CLINICAL TRIALS

In the United States, despite racial and ethnic minority groups making up nearly half of the population, their participation in clinical trials remains disproportionately low. Black or African Americans constitute only about 5% of clinical trial participants, while Hispanic or Latino individuals account for less than 1%.[3,4] Similarly, minority groups in Europe are also underrepresented in clinical trials, impacting the inclusivity and generalizability of research findings.[2] In Japan, although the Pharmaceuticals and Medical Devices Agency (PMDA) acknowledges the importance of demographic diversity in clinical trials, minority representation continues to be insufficient.[9] This global underrepresentation highlights the need for more inclusive strategies to ensure diverse populations are adequately represented in clinical research.

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Recognizing the ethical and scientific necessity of including diverse populations in clinical trials, regulatory bodies worldwide, including the US Food and Drug Administration (FDA), European Medicines Agency (EMA), Health Canada, Japan's PMDA, the International Council for Harmonisation (ICH), and the World Health Organization (WHO), have issued guidelines advocating for the collection and analysis of demographic data.[10,11] These guidelines aim to identify any differential effects and enhance the safety and efficacy of medical treatments for all populations. This global commitment to equitable and inclusive clinical research seeks to ensure that trial results are robust and generalizable across different populations, leading to better-informed healthcare decisions.

However, despite these efforts, concerns remain about the pharmaceutical industry's significant influence on regulatory bodies. Organizations such as the ICH are often perceived as being heavily influenced by industry interests, which raises doubts about their ability to fully prioritize public health.[12,13] While some multinational pharmaceutical companies have taken steps toward greater inclusivity in clinical research—as discussed later in this article—these initiatives are often fragmented and lack uniformity across the industry.[14,15] As a result, relying solely on the goodwill of pharmaceutical corporations is insufficient to effectively address the systemic underrepresentation of minority groups in clinical trials. A coordinated approach, backed by regulatory and governmental oversight, is essential to ensure meaningful progress.[13,16]

ROLE OF GOVERNMENT IN ENFORCING DIVERSITY

Although regulatory bodies such as the FDA and EMA play a crucial role in setting diversity guidelines, they often lack the necessary enforcement mechanisms to ensure compliance, particularly in an industry dominated by influential pharmaceutical corporations.[14] This challenge underscores the need for more proactive government intervention to establish clear, actionable diversity mandates and enforce accountability within clinical trial frameworks.[13,16] For example, there is a pressing need for greater transparency regarding the use of demographic data collected to monitor diversity and how trial designs are adapted to reflect these insights.[12] Without well-defined standards for reporting and applying demographic data, diversity risks becoming an aspirational goal rather than an integral part of clinical research.[13,15]

Research supports the effectiveness of government mandates requiring comprehensive diversity plans as a prerequisite for clinical trial approval. A study published in the New England Journal of Medicine, NEJM (2020) found that trials with explicit recruitment goals for underrepresented groups saw a 15% increase in minority enrolment compared to those without such plans.[17] Furthermore, successful models from other regulatory frameworks, such as the European Union's General Data Protection Regulation (GDPR), demonstrate that imposing significant financial penalties for non-compliance has been highly effective in driving adherence to established standards. Applying similar enforcement mechanisms to clinical research could ensure that diversity becomes a non-negotiable legal requirement rather than an aspirational goal for trial sponsors.

In addition to regulatory measures, financial incentives for participants have proven effective in increasing trial participation among minority groups. For instance, The Lancet (2020) reported that compensation for trial participation during the COVID-19 vaccine rollout in minority communities led to a 25% increase in participation among economically disadvantaged groups.[8] By offering subsidies to cover costs such as transportation, time off work, or other financial burdens, governments could make clinical trial involvement more accessible to underrepresented populations.

HEALTH DISPARITIES AND UNDERREPRESENTATION IN CLINICAL RESEARCH

However, addressing these financial and logistical barriers is only one piece of the puzzle. To fully tackle the underrepresentation of minority groups in clinical trials, it is crucial to acknowledge the deeply rooted historical and systemic factors that have contributed to this issue. Understanding these factors is essential for creating more effective solutions, particularly through digital innovations.

The COVID-19 pandemic underscored substantial disparities in vaccine distribution and clinical trial participation across both high-income and developing countries, offering a clear illustration of global inequities in healthcare access and infrastructure.[18] In the Global South, COVID-19 vaccination campaigns initially faced significant challenges related to vaccine hesitancy and supply chain disruptions. Vaccine hesitancy in these regions was often driven by a lack of trust in government and healthcare systems, stemming from historical instances of medical exploitation and misinformation.[11] This mistrust was exacerbated by the rapid development and approval of COVID-19 vaccines, leading to public scepticism about their safety and efficacy.

Despite international initiatives such as COVAX,

logistical issues further complicated vaccination efforts. The global competition for vaccine doses meant that low- and middle-income countries often found themselves at the back of the line for vaccine procurement. Many developing countries struggled with inadequate healthcare infrastructure, which limited their capacity to store and distribute vaccines, especially those requiring cold chain storage.[18] Rural and remote areas were particularly hard-hit, facing severe difficulties in reaching populations with limited transportation and communication networks.

High-income countries, while better equipped to handle these challenges due to robust healthcare infrastructures, advanced logistics, and greater financial resources, also faced significant hurdles. Vaccine hesitancy, fuelled by propaganda and political polarization, disproportionately affected marginalized communities, including racial and ethnic minorities, economically disadvantaged groups, and individuals with limited access to healthcare. In the United States, for instance, misinformation about vaccine safety and effectiveness spread widely through social media, leading to lower vaccination rates in communities already facing systemic healthcare disparities.[1,7]

LEVERAGING DIGITAL INNOVATIONS TO ENHANCE DIVERSITY & INCLUSION

In the current pharmaceutical landscape, where the treatment of chronic diseases often involves complex polypharmacy, the potential of digital innovations becomes even more critical. The rise of AI and machine learning (ML) technologies have revolutionized many sectors by leveraging vast datasets to create more efficient, scalable, and personalized engagement.[19,20] However, the increasing complexity of medication regimens, paired with growing public scepticism of AI, privacy concerns, and the widespread influence of misinformation, complicates the adoption of these technologies in healthcare. Public uncertainty, fuelled by the often-conflicting narratives on social media, has led to doubts about the promises of AI and its potential for improving health outcomes.[21,22]

Despite the challenges associated with public scepticism and concerns around AI, these technologies have the potential to significantly enhance inclusivity in clinical trials. Leading pharmaceutical companies are already incorporating AI into their trial processes, demonstrating its transformative role in overcoming traditional barriers in clinical research. For instance, AI can analyse vast datasets, optimizing recruitment strategies, and facilitating real-time monitoring, thereby improving both the inclusivity and effectiveness of clinical trials.[23] By integrating diverse data sources—such as clinical records, genetic information, lifestyle factors, and even social media activity—AI technologies offer a more holistic view of potential participants and their behaviours.[24] This multifaceted data integration allows researchers to identify suitable candidates for trials with greater precision, expanding the reach of recruitment efforts, particularly to underrepresented groups.

To further buttress, IBM has leveraged AI-driven platforms to enhance the speed, volume, and diversity of clinical trials. By transitioning to telehealth, real-time monitoring, and AI-driven analytics, IBM's solutions have overcome traditional, time-consuming, and resource-intensive hurdles in patient enrolment. This has enabled more adaptive and responsive trial designs that foster greater diversity.[25] However, for digital operating models to truly succeed, they require a critical mass of users. The effectiveness and efficiency of AI and ML systems improve as they process more data.[26]

In the context of clinical trials, a larger and more diverse pool of participants provides richer data, which refines AI algorithms, leading to better-targeted recruitment and more accurate outcomes. Achieving the necessary "network effect", where AI systems become more valuable as more users participate, is crucial for the success of digital strategies in clinical research (Figure 1).[26] However, this depends on both increasing user trust and addressing the concerns surrounding privacy and data security in digital healthcare.

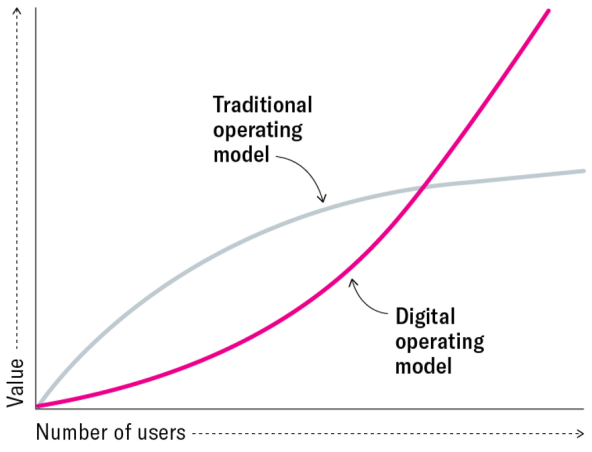

Figure 1. Where digital collides with traditional operating models. Harvard Business Review. Competing in the age of AI, by Marco Iansiti and Karim R Lakhani, January to February 2020. Available from: https://hbr.org/2020/01/competing-in-the-age-of-ai.

Supported by regulatory bodies like the FDA, decentralized clinical trials (DCTs) utilize telehealth technologies, such as remote monitoring devices, telemedicine consultations, and digital platforms for collecting

patient-reported outcomes (PROs). These innovations have demonstrated significant improvements in the convenience and accessibility of clinical trials, particularly in underserved communities. For instance, Pfizer's virtual trial designs during the COVID-19 pandemic proved effective in reaching a broader demographic, especially benefiting individuals in rural and underserved areas who face logistical challenges accessing healthcare facilities. These clinical studies utilized telehealth for remote consultations and monitoring, reducing the need for frequent site visits and thereby facilitating patient engagement from diverse geographic locations.[27]

Relatedly, Roche/Genentech implemented smartwatch and smartphone applications for participants in Parkinson's and Alzheimer's disease studies to track medication compliance and symptoms remotely. This not only broadened the participant pool but also ensured that data was more comprehensive and representative by continuously collecting real-time information on patient health status across different demographics. However, while remote approaches increase accessibility and diversity, they can introduce variability in data collection due to differences in participants' adherence to the protocol and potential technical issues. Therefore, rigorous validation is necessary to ensure data quality, as these factors can affect the accuracy and consistency of the collected data, potentially compromising the integrity of the trial outcomes.[28]

Mobile-friendly platforms for electronic consent and real-time data collection have also been shown to improve participation rates among diverse populations. These applications facilitate easier access to clinical trial information and streamline the enrolment process, making participation more convenient and less burdensome, particularly for individuals with limited access to traditional healthcare facilities. For instance, in regions like the Texas-Mexico border, the Jeeva eClinical Cloud software for electronic consent (eConsent) and biospecimen collection has facilitated faster and more accurate data collection. This technology has also effectively engaged elderly Hispanic individuals with liver and gastrointestinal disorders, enhancing community involvement and ensuring more inclusive data representation.[29]

In the same manner, Sanofi has utilized social media and other digital patient recruitment platforms to facilitate easier access to trial information and enrolment processes. This strategy has effectively increased the inclusion of diverse demographics in their studies.[30] Janssen's Research Includes Me initiative focuses on diversity, equity, and inclusion by employing digital platforms to engage with underrepresented communities. The program provides educational materials and facilitates access to clinical trials.[31] In 2022, the initiative reached over 84 million people with messages emphasizing the importance of diverse representation, illustrating how digital outreach can build trust and increase participation among minority populations.[32]

CONCLUSION

The COVID-19 pandemic starkly exposed and exacerbated the longstanding health disparities and underrepresentation of diverse populations in clinical research. Addressing these issues and fostering trust are crucial for enhancing diversity and inclusivity in clinical trials, ultimately leading to equitable health benefits for all demographic groups. Digital innovations hold significant promise in bridging these gaps. Case studies from Pfizer, Roche/Genentech, Sanofi and Janssen illustrate how technologies like telehealth, AI-driven platforms, and mobile-friendly applications facilitate easier access to clinical trial information, streamline enrolment, and ensure continuous real-time data collection. Decentralized clinical trials (DCTs) using these technologies have shown notable improvements in accessibility and convenience, particularly benefiting individuals in rural and underserved areas.

However, the success of digital operating models in clinical research centres on achieving a critical mass of users. The network effect, where the system's value increases with more users, is vital. Building the necessary infrastructure to support larger and more diverse data pools, refining AI and ML algorithms, and ensuring reliable internet access and user-friendly platforms are essential steps. Additionally, continued regulatory support from bodies such as the FDA, EMA, and WHO is crucial to standardize practices and ensure the integrity of digital trials.

However, building an inclusive clinical trial landscape requires more than technological innovation. It demands collective efforts from regulatory bodies, government entities, and pharmaceutical companies to embed diversity as a legal and ethical standard. Governments can play a pivotal role by mandating the submission of comprehensive diversity plans, offering financial incentives, and enforcing penalties for non-compliance. This regulatory and governmental accountability, paired with the ethical integration of digital innovations, will ensure clinical trials reflect the populations they aim to serve, leading to more equitable and representative healthcare outcomes for diverse populations worldwide.

DECLARATIONS

Author contributions

The author has accepted responsibility for the entire

content of this manuscript and approved its submission.

Conflicts of interest

There is no conflict of interest among the authors.

Data sharing statement

No additional data is available.

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